

[ EMBED  
Presentation  
Drawing  
14 \\*  
MERGEFO

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** December 5, 2017

**SUBJECT:** Response to Public Comments Received on the Aldicarb Proposed Interim  
Registration Review Decision

**PC Code:** 098301

**Decision No.:** 533175

**Petition No.:** NA

**Risk Assessment Type:** NA

**TXR No.:** NA

**MRID No.:** NA

**DP Barcode:** 442715

**Registration No.:** NA

**Regulatory Action:** NA

**Case No.:** 7016

**CAS No.:** 116-06-3

**40 CFR:** §180.269

**FROM:** William Donovan, Chemist  
Ume Hassan, Biologist  
Kelly Lowe, Environmental Scientist  
Risk Assessment Branch V/VII  
Health Effects Division (7509P)

**THROUGH:** Michael Metzger, Chief  
Risk Assessment Branch V/VII  
Health Effects Division (7509P)

**TO:** Kevin Costello, Acting Branch Chief  
Susan Bartow, Chemical Review Manager  
Risk Management and Implementation Branch IV  
Pesticide Re-evaluation Division (PRD; 7508P)

Comments regarding the Aldicarb Proposed Interim Registration Review Decision [Docket Number EPA-HQ-OPP-2012-0161] were received from AgLogic Chemical, LLC. The Health Effects Division (HED) has considered the issues relevant to the human health risk assessment and provides responses that follow. The page, paragraph and line references given at the end of each quoted EPA Statement refer to the Proposed Interim Registration Review Decision document.

**EPA Statement #1:** “Aldicarb products are registered for use to control soil borne pests including mites, various insects, and nematodes.” Page 4 Paragraph 1 Lines 2 – 3.

**AgLogic Comment #1:** This sentence should read, “Aldicarb products are registered for use to control certain insects, mites, and nematodes.” The AgLogic labels do not include soil borne pests other than nematodes and insects such as the seedcorn maggot and the sugar beet root maggot.

**HED Response #1:** HED acknowledges receipt of the information from AgLogic and will correct the description of pests to be consistent with current label language into any updated risk assessments for aldicarb.

**EPA Statement #2:** “Aldicarb may be applied as a soil treatment by any of the following methods: sidedress, band/T-band, and in-furrow treatment. When applied as a post-emergence application to peanuts (pegging application), aldicarb may be applied in a band 12 to 18 inches wide onto the row and into the plant canopy. The granules must be dislodged from the plant and the application should be followed immediately by irrigation (unless rainfall is received).” Page 5 Paragraph 1 Lines 4 – 9.

**AgLogic Comment #2:** Mitigation measures which counter any adverse effects from application methods described above have been proposed by AgLogic, and can be found in Appendix D of the Interim Decision Document. AgLogic agrees with the mitigation language identified in the proposed Interim Decision and has already incorporated the mitigation language in its AgLogic 15GG label and will also amend the AgLogic 15G label with the agreed upon mitigation language. AgLogic requests that these mitigation measures and refined PCT data be incorporated into an updated, revised dietary risk assessment and that the Interim Decision document be updated accordingly, so that those reading the final decision document can be assured that the registered uses of aldicarb do in fact meet the criteria of “reasonable certainty of no harm.”

**HED Response #2:** HED has updated the dietary risk assessment to take into account revisions to PCT values by the Biological and Economic Analysis Division (BEAD), and addressing drinking water risks using a DWLOC approach (D444345, W. Donovan, 28-NOV-2017).

**EPA Statement #3:** “A highly refined acute dietary (food only) exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) for all existing food uses of aldicarb. Estimated acute dietary exposure and risk estimates are below EPA’s level of concern (LOC) for the U.S. population and all population subgroups. Exposure is equivalent to 25% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure for the general U.S. population and 65% of the aPAD for the highest exposed population subgroup, children 1 to 2 years old.” Page 6 Paragraph 3 Entire Paragraph.

**AgLogic Comment #3:** A revised dietary assessment based on more realistic percent crop treated numbers as well as revised water modeling based on label modifications resulted in an

aldicarb acute dietary exposure for food and drinking water equivalent to 25% of the aRfD (aPAD) at the 99.9th percentile of exposure for the general U.S. population and 54.13% of the aRfD (aPAD) for the most exposed subpopulation, children age 1-2.

**HED Response #3:** HED has updated the dietary risk assessment to take into account revisions to PCT values by BEAD, and addressing drinking water risks using a DWLOC approach (D444345, W. Donovan, 28-NOV-2017). To the extent that the BEAD PCT values differ from those assumed by AgLogic, the resulting dietary risk levels may be expected to differ from the values cited above. For example, AgLogic assumes zero PCT for orange juice, which is a risk driver for aldicarb. BEAD has recommended use of 20% crop treated for orange juice in the acute dietary assessment (Memo, D. Atwood, 01-MAR-2017). Consequently, the revised dietary assessment shows higher exposure values than those calculated by AgLogic.

**EPA Statement: #4** “The CSA results in worst case exposure estimates above the LOC for children following the consumption of an estimated single serving of sweet potato (domestic and import) or potato (import). These estimates represent exposures beyond the 99.9th percentile considered as the point of regulation for the Agency’s highly refined human health dietary risk assessments. A similar analysis performed for other crops to which aldicarb can be applied did not result in estimated exposures that would exceed an LOC.” Page 6 Paragraph 4 Lines 7 - 12.

**AgLogic Comment #4:** EPA notes that the worst case exposure is above the LOC for children for sweet potato and potato, but also notes that this analysis “represents exposures beyond the 99.9th percentile considered as the point of regulation for the Agency’s highly refined human health dietary risk assessment.” It should also be noted that there is low probability of a child consuming the “single serving” indicated by the Agency. Therefore, available data shows that use of aldicarb as indicated in this assessment meets the criteria of “reasonable certainty of no harm” for the general U.S. population and for all subpopulations, including children.

**HED Response #4:** HED has updated the dietary risk assessment to take into account revisions to PCT values by BEAD, and addressing drinking water risks using a DWLOC approach (D444345, W. Donovan, 28-NOV-2017). The previous CSA analysis for potato was omitted as new information indicates that no aldicarb-treated fresh potatoes are imported and there is no domestic aldicarb use on potato. While the Agency typically uses the 99.9th percentile as a benchmark in assessing risk concern, the characterization of risk is related to the degree of refinement of each specific risk assessment. In cases such as aldicarb for which the assessment is highly refined, characterization of risks using the CSA approach is appropriate since it may identify real risk concerns not identified using the standard dietary assessment approach. HED notes that, based on PDP monitoring data from 2008-2010, only two samples out of 1476 had residues above the level of concern for preschoolers. Thus, the risks identified by CSA should be considered to represent rare consumption events.

**EPA Statement #5:** “The label-required Personal Protective Equipment (PPE) varies depending on the handling scenario and packaging of the formulation (i.e., substrate of the granular formulation).” Page 8 Paragraph 6 Lines 1 – 2.

**AgLogic Comment #5:** This sentence should read, “The label-required Personal Protective Equipment (PPE) varies depending on the handling scenario.” It is important to note that both the corn cob grit formulation and the gypsum formulation have ultra-low dust levels (typically less than 0.02% dust) and, therefore, the packaging and PPE are the same for both formulations. The Interim Decision cited the low dust levels Page 31 (Paragraph 4, Lines 3-5): “The two registered aldicarb products are granular products with a concentration of 15% active ingredient, which have either a low-dust corn cob grit or vinyl-coated gypsum-based substrate, and are considered low-dust formulations.”

**HED Response #5:** HED acknowledges receipt of the information from AgLogic and will correct the PPE requirements to be consistent with current label language into any updated risk assessments for aldicarb.

**EPA Statement #6:** “This risk was driven by the dermal component. Mixer/loader risk estimates are of concern for the use on sugar beets at the maximum rate of 4.95 lb ai/A (MOE = 4.5) for nematode control and the maximum rate of 3 lb ai/A (MOE = 7.4) for control of other pests listed on the label, see table 3.” Page 9 Paragraph 3 Lines 9 – 12 and Table 3.

**AgLogic Comment #6:** The two most important points that need to be considered when determining the risk associated with worker exposure to aldicarb during application to sugar beets are (1) the actual acres treated in a given day and (2) the documented half-life of aldicarb cholinesterase inhibition in the human body as a result of reversibility of effects. The 2007 EPA assessment of worker risks from use of aldicarb used the following factors to estimate handler exposure and risk, and are considered typical for HED handler assessments:

- Exposures were assessed for an 8-hour occupational workday.
- Daily acres treated/day assumptions were 80 acres for orchard and field crops; 50 acres for coffee plantations; and 10 acres for ornamentals.
- Risk estimates were calculated based on an endpoint identified in a human study which has been recently evaluated by the Agency’s Human Studies Review Board and deemed appropriate for risk assessment.
- Exposures were based on maximum application rates for representative crops.
- The average body weight for an adult handler is 70 kg.

The 2016 EPA assessment indicates that the daily treated acres for sugar beets is 200. This number, according to the footnotes, is based on the Exposure Science Advisory Council Policy #9.1. This change from 80 acres per day to 200 acres per day increases the exposure by 2.5X. The 2007 assessment results in an MOE=9.4 for worker exposure from treating 80 acres of sugar beets at 6 lb ai/acre, which the Agency states is “just slightly below the risk targets” of MOE = 10.

The Exposure Science Advisory Council Policy #9.1 states that “This is a reference for exposure assessors to use when there are no acceptable data regarding the number of acres that a pesticide handler can treat per day with a specific pesticide.” It further states that “the values here are considered to be ‘typical-to-high-end.’ These values should be modified by pesticide- and crop-specific knowledge that affects the number of acres that can be treated in a day.”

The policy document states that for “loading granulars” 40 acres per day should be used for “golf courses,” 80 acres per day for “typical field crops and sod farm broadcast treatments” and 200 acres per day as an “upper range for high acre crops including, but not limited to cotton, corn, wheat, alfalfa, rice and soybeans.”

EPA has not provided a justification for changing the assumption of the number of acres treated in a day from 80 to 200 acres in the 2007 and 2016 assessments, respectively. In addition, EPA has not considered the appropriate number of acres of sugar beets that can be treated with aldicarb in one day.

The following assumptions should be considered for aldicarb applications to sugar beets:

- There is one worker, the handler/loader/tractor driver, and he
  - Loads the bags into the hopper boxes
  - Drives the tractor applying the AgLogic 15GG
  - Cleans up and properly disposes of the empty boxes and bags.
- It takes approximately 1.5 minutes to open the outer box, open the bag and empty each bag into the hopper, for a total of approximately 90 minutes to empty the 59 bags required to treat 80 acres at the high rate of 33 lbs of AgLogic 15GG (4.95 lbs ai)/A.
- The sugar beets are planted on 30-inch row spacing, resulting in approximately 22 miles of travel for the tractor.
- It will take approximately one (1) hour to make all row-end turns.

Using the above assumptions, a tractor with a typical 12-row planter traveling at 6.0 mph could cover (treat) an average 80-acre field in about 4.5 hrs without any stops for filling the hoppers, which is estimated at approximately 1.5 hours, for a total of 6 hours. These calculations do not include any time for travel to and from the field, disposal of the boxes and bags, and for cleaning and maintenance of the equipment.

The above discussion would indicate that, when one considers the details of applying AgLogic 15GG to sugar beets, it is unreasonable to assume that 200 acres could be treated in one eight-hour occupational work day. The 80 acres per day for a “typical field crop” would be a more reasonable number. Calculation of the exposure for the mixer/loader based on 80 acres per day results in an MOE=11.94, clearly above the desired MOE=10. Even if 100 acres of sugar beets are treated the MOE = 9.6 which according to the 2007 Agency assessment would be “just slightly below the risk targets.”

Secondly, when conducting a worker exposure and risk assessment for application of aldicarb to sugar beets, the documented reversibility of aldicarb cholinesterase (ChE) inhibition needs to be considered. Based on available data the Agency has determined “an estimated half-life for red blood cell (RBC) cholinesterase (ChE) inhibition of two hours which is based on data of aldicarb from rats and human subjects.”

Based on a two-hour half-life for cholinesterase (ChE) inhibition, the effects of the any given exposure would be reduced to 50% two hours after that exposure. This means that for an eight-

hour occupational work day, at the end of the day the cholinesterase inhibition from the initial exposure would be reduced to 6.25% of the original effects.

Therefore, in evaluating the worker risk resulting from exposure to aldicarb during application of AgLogic 15GG to sugar beets consideration of the actual number of acres that could be treated in one day and the reversibility of aldicarb cholinesterase effects in the human body would demonstrate that the risk to workers is not of concern. Furthermore, consideration should be given to the likelihood that the dermal absorption of aldicarb is not 100% as assumed in these calculations.

**HED Response #6:** Potential risk concerns have been identified for mixers/loaders who would be loading application equipment with granular aldicarb products for use at-planting on sugar beets.

Because HED's assessments assume that a worker would plant 200 acres of sugar beets per day and load all of the necessary pesticide for such an application in one single exposure event, BEAD has provided information to HED for refinement of exposure estimates. BEAD determined the maximum likely area that could be treated in one day. Depending on the planting equipment used, 50 acres (12-row planter) to 105 acres (24-row planter) of sugar beets could be planted per 8-hour day (Memo, J. Becker and C. Myers, 01-NOV-2017).

HED used the recent information from BEAD as a refinement of assumptions to calculate updated occupational handler risks. Assuming 105 acres and one mixing/loading event representing a bolus dose, the MOE for mixing/loading granules for sugar beets is 8.5 with an LOC of 10. While it is possible for a mixer/loader to be exposed to the entire amount handled once per day, HED acknowledges that it is likely that the full amount of product is not loaded in one event per day; therefore, multiple mixing/loading events could be considered and inclusion of the aldicarb cholinesterase inhibition half-life into the occupational assessment could be a reasonable refinement. Using the revised acreage listed above (i.e., 105 acres) split into two events separated by 2 hours, and including the aldicarb cholinesterase inhibition half-life, the MOE for mixing/loading granules for sugar beets is 11 with a LOC of 10. When considering these risk estimates, the following points are also acknowledged by HED:

1. A default 100% dermal absorption factor was used to estimate the dermal dose. Given that aldicarb is handled only as a granular, it is unlikely that 100% absorption would occur; however, the exact absorption factor could not be determined from the available toxicological studies;
2. The 105-acre/day BEAD estimate is considered high-end for at-plant tractor granule herbicide applications;
3. Information regarding the flux rate of aldicarb through the skin is not available, therefore, the calculation assumes immediate absorption through the skin; and
4. The calculation assumes the maximum application rate of 4.95 lb ai/A.

**EPA Statement #7:** "860.1650 Submittal of Analytical Reference Standards: Analytical standards for aldicarb (CAS# 116-06-3) and its metabolites aldicarb sulfoxide (CAS# 1646-87-3) and aldicarb sulfone (CAS# 1646-88-4) currently are not available at the EPA National Pesticide

Standards Repository. Fresh samples of these standards must be submitted as soon as possible.”  
Page 11 Section A. Human Health Risk, Subsection 4. Human Health Data Needs.

**AgLogic Comment #7:** AgLogic is in the process of sending these standards to the EPA repository. Also, please be aware that AgLogic has provided standards to the EPA repository every time they have been requested by EPA (March 2016, January 2017 and July 2017).

**HED Response #7:** This issue will be resolved upon receipt of the requested standards.

**EPA Statement #8:** “Mitigation measures proposed by the registrant during the public comment period are expected to reduce the acute drinking water exposure estimates. In addition, EPA received and verified refined domestic percent crop treated (PCT) information for sweet potatoes, and percent of imported commodity in domestic consumption for oranges, orange juice, and potatoes. The acute dietary exposure estimates are expected to decrease as a result of the mitigation measures proposed by the registrant, the refined PCT information, and updated percent of imported commodities.” Page 24 Paragraph 3 Entire Paragraph.

**AgLogic Comment #8:** The Agency further states (page 25, paragraph 2, line 5) that “. . . the proposed mitigation would reduce the EDWCs for surface water to zero.” Therefore, AgLogic requests that these mitigation measures and refined PCT data be incorporated into an updated, revised dietary risk assessment, that the Interim Decision document be updated accordingly, and the extremely large exposure estimates in the current document, especially for drinking water, be revised. This is important so that those reading the final decision document can be assured that the registered uses of aldicarb do in fact meet the criteria of “reasonable certainty of no harm.”

**HED Response #8:** HED has updated the dietary risk assessment to take into account revisions to PCT values by BEAD, and addressing drinking water risks using a DWLOC approach (D444345, W. Donovan, 28-NOV-2017).